

SUBJECT: PRODUCT CHEMISTRY REVIEW OF:

DP Barcode: 246426

Reg. No. Or File Symbol: 10182-UUR

Manufacturing-use [X]

OR End-use Product [X]

TO:

Martha Terry

PM team No. 33

FROM:

Nancy Whyte, Chemist *NW 6/23/98*
Efficacy and Science Support Branch, Team 2
Antimicrobials Division (7510W)

THRU:

Michele Wingfield, Acting Chief
Efficacy and Science Support Branch
Antimicrobials Division (7510W)

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SUMMARY OF INFORMATION REVIEWED AND FINDINGS

- The is a new product whose active ingredient is also under review for registration. A full data package was submitted for product chemistry review as required by 40 CFR, Part 158, Guidelines 61,62, 63. The plasticizer used in this product and in the parent product has been approved for food use by 21 CFR, 181.27, although food use is not suggested by the label. The data reviewed is attached. The product chemistry data is acceptable and meets all requirements.

PRODUCT CHEMISTRY REVIEW

4. CONFIDENTIAL STATEMENT OF FORMULA

4a. Type of formulation and source registration

- Non-integrated formulation system [X]
 - Are all TGAIs used registered? Yes [] No [X]
- Integrated formulation system []
- if "ME-TOO", specify EPA Reg. # of existing product:

4b. Clearance of inerts for non-food or food use:

NA

Cleared for food use under 40 CFR §180.1001: Yes [] No [] NA [X]
 If Yes: c [] d [] e []

4c. Physical state of product: liquid

4d. The chemical IDs and analytical information (including that for the TGAIs), density, pH, and flammability are consistent with that given in GRN 61, 62, and 63-7, 63-12, and 63-15, respectively: Yes [X] No []

4h. NCs and CLs are acceptable: [X] Not acceptable []

4i. Active ingredient (s) NC LCL UCL

A. N-Butyl-1,2-benzisothiazolin-3-one 9.5 9.0 9.9

4j. For products produced by an integrated formulation system:

- All impurities of toxicological significance have a UCL?
 Yes [] No [] Not applicable [X]
- All impurities of $\geq 0.1\%$ in the product have been identified?
 Yes [] No [] Not applicable [X]

5. PRODUCT LABEL

- 5a. The active ingredients statement (chemical IDs and NC) is consistent with the CSF? Yes [X] No []
- 5b. The formulation contains one of the following:
- 10% or more of a petroleum distillate: Yes [] No [X]
 - 1.0% or more of methyl alcohol: Yes [] No [X]
 - Sodium nitrite at any level: Yes [] No [X]
 - a toxic List 1 inert at any level: Yes [] No [X]
 - arsenic in any form: Yes [] No [X]
- 5c. If Yes to any of the above, does the inert ingredients statement contain a footnote indicating this? Yes [] No [] Not applicable [X]
- 5d. The appropriate warning statement regarding flammability or explosive characteristics of the product are listed on the label?
 Yes [] No [] Not applicable [X]
- 5e. The storage and disposal instructions for the pesticide and container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses? Yes [X] No []
- 5f. Does the product require an expiration date at which time the NC falls below the LCL (based on the one year storage stability data or other information)?
 Yes [] No [X]

6. PRODUCT CHEMISTRY (GRN 61, 62, 63)

	Acceptance of Information	MRID No.
61-1 Chemical ID (See Appendix) ¹	A	443647-01
61-2a Manufacturing Process ²	A	443647-02
61-2b Formulation Method ³	A	443647-02
61-3 Discussion of Impurities ⁴	A	443647-03
62-1 Analysis ⁵	A	443647-04
62-2 Certified Limits ⁶	A	443647-01
62-3 Analytical Method for Ais ⁷	IF, HPLC, Mass Spectrum	444109-01

Explanation: A=acceptable; N=not acceptable; NA=technically not applicable; G=data gap; U=requires upgrading; W=waived; E=EPA estimate.

¹See Confidential Appendix A for additional information

²For MP/EP products produced by an integrated formulation system.

³For products from a TGAI or MP.

⁴May be waived unless actual/possible impurities are of tox concern.

⁵Five batch analysis required for products produced by an integrated formulation system.

⁶If different from standard CIs recommended in 40 CFR 158.175, this should be discussed in Confidential Appendix A.

⁷Abbreviate method used as follows: gas chromatography (GC), infrared (IR), ultraviolet absorption (UV), nuclear magnetic resonance (NMR), etc.

6b. <u>Physical/Chemical Properties*</u>	Acceptance of data	Value or qualitative description	MRID No.
63-3 Physical State and Color	A	slightly viscous liquid Pale yellow	444109-01
63-4 Odor	A	slightly acrid odor	444109-01
63-7 Density	A	1.00 at 20° C.	444109-01
<u>63-12 pH of Product¹</u>	<u>NA</u>		<u>444109-01</u>
63-15a Flash Point (° C) ²	196 +/- 4° C		444109-01
63-15b Flame Extension	NA		
63-16 Explodability	A	Not explosive	444109-01
63-17 Storage Stability (% degradation of AIs at 20-30 ° C for ≥ 1 yr.)	A	14 day test study 1 year study pending	444109-01
63-18 Viscosity	A	56 mPS at 25° C.	444109-01
63-19 Miscibility (with hydrocarbon solvents) ³	NA		
63-20 Corrosivity (specify metals/conditions)	A	None detected	444109-01
63-21 Dielectric Breakdown Voltage ⁴	NA		

Explanation: A=acceptable; N=not acceptable; NA=technically not applicable; G=data gap; U=requires upgrading; W=waived; E=EPA estimate.

* Provide brief description, e.g., color--yellow or property value, e.g., density 1.25 g/cc; Unless otherwise indicated, the property should be at 25 °C.⁵

¹ If product is a water solution or dispersion.

² Not required for aerosols.

³ Emulsifiable liquids only.

⁴ For end-use products near electrical equipment.